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Applicant(s): Haskell E. MULLINS et al.

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Title: AUTOMATED RESPIRATOR FIT TESTING METHOD AND SYSTEM

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We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

 Utility Patent Application: Specification (18 pgs); Claims (36 claims on 6 pgs); 1 pg Abstract. 2 Sheets of informal drawings. A signed Declaration and Power of Attorney (3 pgs). A return postcard. An Assignment of the invention to 3M Innovative Properties Company and Recordation Form Cover Sheet (3 pgs). A check in the amount of \$40.00 to cover the Assignment Recording Fee. A check in the amount of \$998.00 to cover the filing fee, which is calculated below:

APPLICATION FILING FEE

	Number of Claims Filed (1)	Claims Included in Basic Filing Fee (2)	Number of Extra Claims (1-2)	Cost per Extra Claim	Fee Required
Total Claims	36	-20 =	16	x \$18 =	\$288
Independent Claims	3	-3	0	x \$80 =	\$0
One or More Multiple-Dependent Claims Presented? If Yes, Enter \$270 Here →					\$0
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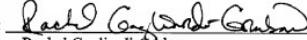
By: 
Name: Kevin W. Raasch
Reg. No.: 35,651
Direct Dial: 612-305-1218
Facsimile: 612-305-1228

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AUTOMATED RESPIRATOR FIT TESTING METHOD AND SYSTEM

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The present invention relates to an automated respirator fit testing method and system.

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Background

Respirators are worn over at least the mouth and nose of a person for two common purposes: (1) to prevent impurities or contaminants from entering the wearer's breathing tract; and/or (2) to protect others from being exposed to pathogens and other contaminants exhaled by the wearer. In the first situation, 15 the respirator is worn in an environment where the air contains particles harmful to the wearer, for example, in an auto body shop. In the second situation, the respirator is worn in an environment where there is a high risk of infection, for example, in an operating room. To accomplish either of these purposes, a snug fit to the wearer's face must be maintained.

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Respirators are commonly fit tested to determine whether they have the proper size or shape and whether they can be adjusted to provide an adequate seal between the respirators and the wearers' faces. Respirator fit testing has been required by various government agencies. In the United States, respirator fit testing is regulated according to 29 C.F.R. § 1910.134 (Appendix 25 A). The regulations vary depending on the type of test being performed, for example, whether the removal efficiency of the respirator is 95%, 99%, or 99.97%.

Qualitative respirator fit testing typically involves a one-on-one test conducted by a trained test administrator on a test subject. The test subject dons a 30 respirator and, within a controlled environment, is exposed to an aerosol that can be detected by taste or odor. The aerosols that are used in taste response testing are generated manually by a test administrator using a squeeze bulb attached to a nebulizer. The test typically involves having the test subject perform a variety of

exercises, such as deep breathing, head rotation, etc., to assess the viability of the seal under conditions that may be encountered by the test subject.

Variability in respirator test results is one disadvantage of qualitative respirator fit testing. For example, the aerosol concentration levels to which the
5 test subjects are exposed may vary if the test administrators do not manually deliver the same amount of test aerosol. Other fit testing variations may be found in the content and/or timing of prompts provided to the test subjects when directing them to perform activities as a part of the fit testing procedure.

Other disadvantages of known respirator fit testing procedures may
10 include the cost and/or limited availability of trained personnel to carry out the tests for all of the individuals requiring them. In some instances, fit testing may be required in locations that are far removed from the location of trained test administrators. This can require travel by the test administrator or the personnel requiring fit testing to complete the required tests.
15

Summary of the Invention

The present invention addresses a number of the problems that are associated with qualitative respirator fit testing by, in one aspect, providing an automated system and method for the remote administration of qualitative
20 respirator fit tests. In another aspect, the present invention addresses the problems associated with qualitative respirator fit testing by providing a system and method for administering qualitative respirator fit tests to two or more test subjects simultaneously.

Among the methods of the present invention, remote administration of
25 qualitative respirator fit tests involves the testing of test subjects located at one facility by a test administrator located at a different facility. The two facilities may be located, for example, in the same city, in different countries, etc. As a result, a single test administrator may, for example, be able to administrate fit tests with test subjects located in a variety of facilities in one day without
30 traveling. As a further advantage, the same test administrator may be able to conduct fit tests at two or more locations at the same time.

In other variations, the present invention provides an automated qualitative respirator fit testing system and method that is capable of testing two or more individuals at the same time. The system includes multiple test stations and an automated aerosol generator system in fluid communication with each of 5 the test stations. The automated aerosol generator system may be capable of delivering aerosol to the test stations in repeatable, selected amounts and may also be capable of delivering the aerosols to some or all of the stations simultaneously.

Among the advantages of the present invention are an increase in the 10 availability of qualitative respirator fit tests and a corresponding potential decrease in the cost of administering each test. Providing a test administrator with a fit test system including an automated aerosol generator system in fluid communication with multiple test stations enables fit testing of two or more test subjects at the same time using a single fit testing system. As a result, the number 15 of tests conducted by the test administrator may increase and the cost of administering the fit tests may, correspondingly, decrease.

Another advantage of the present invention is the reduction of at least some of the variability in qualitative respirator fit tests. For example, the use of 20 an automated aerosol generator system reduces or eliminates the variability that may be encountered with the use of manual squeeze-bulbs. In addition, in those methods in which the activity prompts are automatically delivered from, e.g., a computerized device, variability in the content and/or timing of prompts provided to test subjects during respirator fit testing can also be reduced or eliminated.

In one aspect, the present invention provides a method of qualitative 25 respirator fit testing that includes providing an automated qualitative respirator fit testing system with a plurality of test stations and an automated aerosol generator system in fluid communication with each of the test stations. The method also includes locating at least one test subject at one test station of the plurality of test stations and conducting a qualitative fit test on each test subject located at one of 30 the test stations. The qualitative fit test includes delivering a test aerosol to the test station using the automated aerosol generator system after locating a

respirator on the test subject, wherein the test subject is exposed to the test aerosol, and receiving test feedback from the test subject at the test station after exposure to the test aerosol. In one alternative, the method may involve locating at least two test subjects at the plurality of test stations and simultaneously 5 conducting two qualitative fit tests on each of the at least two subjects located at the test stations.

In another aspect, the present invention provides a qualitative respirator fit testing system that includes a plurality of test stations and an automated aerosol generator system in fluid communication with each of the test stations. The 10 automated aerosol generator system may include a set of independent aerosol generators, wherein at least one of the independent aerosol generators is in fluid communication with each of the test stations. Alternatively, the automated aerosol generator system may include at least one aerosol generator in fluid communication with at least two of the plurality of test stations.

15 In another aspect, the present invention provides a method of remote respirator fit testing that includes providing an automated respirator fit testing system at a first location, wherein the respirator fit testing system has at least one test station and an automated aerosol generator system in fluid communication with each of the at least one test stations. At least one test subject wearing a 20 respirator is located at the test station. The respirator fit testing system is operated from a remote location to perform a respirator fit test on the test subject by delivering a test aerosol to the test station using the automated aerosol generator system, wherein the at least one test subject is exposed to the test aerosol.

25 These and other features and advantages of the invention may be described in more detail below with reference to various illustrative embodiments of the invention.

Glossary

In reference to the invention, the following terms are defined as set forth below. Other terms may also be explicitly defined in the detailed description or with reference to the specification, claims and drawings.

- 5 “Aerosol” means a gas that contains suspended particles in solid and/or liquid form;
- “automated aerosol generator system” means an aerosol generator system that generates aerosols without the use of manual squeeze bulbs;
- “monitoring” (and variations thereof) means visual observation by a 10 person or machine-based monitoring by a camera or similar device;
- “qualitative respirator fit test” (and variations thereof) means a respirator fit test that relies on the taste and/or smell response of the test subject to detect leakage of a respirator; and
- “respirator” means a system or device worn over a person’s breathing 15 passages to prevent contaminants from entering the wearer’s respiratory tract and/or to protect other persons or things from exposure to pathogens or other contaminants expelled by the wearer during respiration, including, but not limited to filtering face masks.

Brief Description of the Drawings

FIG. 1 is a schematic diagram of one test administrator **50** using a fit testing system **10** including multiple test stations **20**, an automated aerosol generator system **30**, and a controller **40**.

FIG. 2 is a schematic diagram of one aerosol generator system **130**.

25 FIG. 3 is a schematic diagram of one data record **60** including a variety of fit testing information.

FIG. 4 is a schematic diagram of one test administrator **150** using multiple fit testing systems **110**.

Detailed Description of Illustrative Embodiments of the Invention

FIG. 1 is a schematic diagram of one qualitative respirator fit testing system **10** under the control of a test administrator **50**. The fit testing system **10** includes multiple test stations **20** connected to an automated aerosol generator system **30**. The aerosol generator system **30** is controlled by a controller **40** that, in the illustrated embodiment, is operated by the test administrator **50**.

The controller **40** may be provided in any suitable form, e.g., a hardwired control device or a data processing system, e.g., a personal computer or workstation that includes a processor, one or more display devices, one or more input devices, one or more data storage devices, and one or more printers or other output devices. In some instances, the controller may include a combination of one or more hardwired control devices and one or more data processing systems.

The test aerosols generated during qualitative fit testing rely on taste and/or smell response of the test subject for detection. Potential aerosols for qualitative fit testing may include, but are not limited to, isoamyl acetate, saccharin, denatonium benzoate (available under the tradename BITREX from Mcfarlan Smith Company, Edinburgh, UK), stannic chloride, etc. One exemplary test aerosol source solution for use in a Class 95 fit testing protocol (where 95% removal efficiency is required) may be a mixture of 5%bw BITREX in saline solution (using BITREX with a concentration of 1.6875 mg/ml). The same BITREX material can be used to provide a sensitivity aerosol source solution, although the BITREX used is at a concentration of 0.135 mg/ml (again mixed with saline at a 5%bw).

Although the fit testing system **10** is depicted with five test stations **20**, fit testing systems **10** of the present invention may include as few as two test stations **20** or more than five test stations **20** and the depiction of system **10** with five stations should not be construed as limiting to the invention. During fit testing, the test stations **20** each provide an independent environment in which a test subject is exposed to a test aerosol delivered by the automated aerosol generator system **30**. By “independent environment,” it is meant that the test aerosol delivered to one of the test stations **20** cannot be communicated to another of the

test stations **20**. As a result, fit tests can be conducted simultaneously, but independently, at two or more of the test stations **20**.

Each test station **20** will typically include some structure that defines an enclosed volume in which the nose and mouth of a test subject can be located.

- 5 For example, the test stations **20** may be provided in the form of a room or booth in which the test subject may be located. Alternatively, it may be necessary only to provide a testing hood that fits over, e.g., the test subject's head. Such testing hoods are commonly used in connection with respirator fit testing because of their convenience.
- 10 The automated aerosol generator system **30** depicted in connection with fit testing system **10** includes a central aerosol generator in fluid communication with each of the test stations **20** as depicted in FIG. 1. By "fluid communication" as used herein, it is meant that the central aerosol generator system **30** is capable of delivering aerosol to the test stations **20**. In the configuration depicted in FIG.
- 15 1, the central aerosol generator **30** may be in fluid communication with the test stations **20** by fluid conduits, even though those fluid conduits may be closed at any given time by, e.g., valves or other mechanisms. It may be preferred, but not required, that the central aerosol generator system **30** be capable of delivering an aerosol to two or more of the test stations **20** at the same time.
- 20 Also a part of the qualitative fit testing system **10** illustrated in FIG. 1 is a controller **40**. The controller **40** is depicted as being in communication with the aerosol generator system **30** as well as with each of the fit testing stations **20**. The controller **40** preferably provides operating control over the functions of the aerosol generator system **30**, determining such activities as the amounts and times 25 at which the various aerosols used in the fit tests are delivered to each test station **20**. The automated aerosol generator system **30** and controller **40** can be located remote from each other and connected by any suitable technique, e.g., modem, hardwire connection, radio control, computer network connection, etc. Further, although the controller **40** is depicted as separate from the aerosol generator 30 system **30**, the controller **40** and aerosol generator system **30** could be integrated into a single unit, if so desired.

The controller **40** may also optionally be connected to each of the test stations **20**. The connections between the controller **40** and the test stations **20** may be provided for a number of reasons. In some embodiments, the controller **40** may be connected to each of the test stations **20** to receive feedback from the
5 test subjects during the fit testing process. That feedback to the controller **40** may be provided in any suitable manner, e.g., by voice, action by the test subject (such as pressing a button, keyboard, nodding, blinking, etc.), inaction by the test subject, etc. The feedback may be indicative of a number of things, e.g., detection of an aerosol by the test subject, completion of an activity by a test
10 subject, selection of one option from a list of potential choices, etc.

In other embodiments, the controller **40** may be connected to the test stations **20** for a number of other reasons. For example, the controller **40** may provide prompts to the test subjects requesting that they perform certain activities, provide them with information regarding the fit testing process, request that they
15 select a language for conducting the fit test, etc. The prompts may be visible and/or audible to the test subject.

In other cases, the controller **40** may be connected to a monitoring device located at the test station **20** to monitor the test subject during fit testing. The monitoring may be performed by cameras, or it may involve monitoring other
20 physiological responses such as the test subject's pulse, breathing, etc. If performed by cameras, the image or images generated may be captured and stored at the controller **40** or in some other place or device for reference purposes.

The controller **40** may also be connected to one or more devices within the test stations **20** that detect aerosol concentration levels, humidity, temperature,
25 flow rate, etc.

The test administrator **50** is an optional feature of the methods of the present invention. In some instances, the fit testing process may be completed in the absence of test administrator **50** if the fit testing system **10** is capable of providing the prompts required to complete the fit testing process and receive and
30 store the feedback generated by the test subjects during the tests. The presence of a fit test administrator **50** may, however, be helpful if the fit testing system, for

example, lacks the capabilities to operate as a stand-alone device. In other instances, it may be preferred to have someone present at the test location directing and/or monitoring testing to increase the comfort level of the test subjects, insure compliance with test protocols, monitor the equipment for 5 malfunctions, etc. That person may or may not, however, be a trained test administrator. For example, a person may be present merely to attend to the equipment, if necessary.

Due to the nature of the fit testing system **10**, however, it may not be necessary for the test administrator **50** to be physically present in the proximity of 10 the test stations **20**. Because the automated aerosol generator system **30** is used to provide the aerosols used during the fit testing, the test administrator **50** may be located at a remote site and be in communication with the test stations **20** through, e.g., a voice link, voice and video link, text link, etc.

If a test administrator **50** is used to administer the fit tests, the controller 15 **40** may not need to be connected to the test stations **20** as depicted in FIG. 1. Rather, the controller may only operate the aerosol generator system **30** while the test administrator **50** provides the prompts to and receives feedback from the test subjects at the test stations **20**. It may, however, be preferred that the controller **40** issue the prompts to and/or receive feedback from the test subjects to allow the 20 test administrator **50** to address unexpected issues that may be encountered during fit testing.

According to one version of the methods of the present invention, at least one test subject is positioned at one of the test stations **20** of a qualitative fit testing system **10** that includes multiple fit testing stations **20** in fluid 25 communication with an automated aerosol generator system **30**. A qualitative fit test conducted at test station **20** includes delivering a test aerosol using the aerosol delivery system **30**, thereby exposing the test subject at the station **20** to the test aerosol (after the test subject has donned the respirator to be tested). After exposure, test feedback is received from the test subject, indicating, for 30 example, detection or no detection of the test aerosol by the test subject.

- Although the methods of the invention may include testing a single test subject using a fit testing system that includes multiple test stations, it may be preferred that two or more test subjects be positioned at test stations **20**. Fit tests can then be conducted simultaneously on at least two of the test subjects at the 5 test stations **20**. Although the fit tests are conducted simultaneously, it is not necessarily required that each of the fit tests be performed in complete synchronicity. In other words, the fit tests on the different test subjects may progress at different rates, so long as at least two test subjects are engaged in fit testing by the fit testing system **10** at the same time.
- 10 One additional optional feature of methods of the present invention may include, for example, storing the test feedback in a database. That database may, optionally, include personal identification information regarding the test subject being fit tested. In the case of test feedback, that test feedback information may be correlated with the personal identification information of the test subject.
- 15 Other additional optional features of the methods of the present invention may include monitoring each of the test stations **20** during exposure of the test subjects at those stations **20** to the test aerosol. As discussed above, that monitoring may be accomplished in a variety of manners. It may be preferred, however, that the monitoring involve real-time visual monitoring by a test 20 administrator **50** during administration of the tests (e.g., in person, by video link between remote locations, etc.). Visual monitoring may alternatively be accomplished by capturing images of the test subjects during fit testing using, e.g., cameras or similar devices. If one or more images are captured during monitoring of the test stations **20**, the captured image or images may also be 25 stored in the database, preferably correlated to the personal identification information of the appropriate test subject for future reference. It may be preferred that both real-time visual monitoring by a test administrator **50** and visual monitoring by the capture of images be performed in connection with the present invention.
- 30 As a part of the methods of the present invention, it may be preferred that the automated aerosol generator system **30** deliver selected amounts of the test

aerosol to each of the test stations **20** occupied by a test subject at predetermined intervals during at least a portion of the fit testing. The delivery of selected amounts of test aerosol at predetermined time intervals may be useful for establishing and maintaining a desired concentration level of the test aerosol at 5 each test station **20**.

Delivery of test aerosol to the test stations **20** by the automated aerosol generator system **30** may also involve simultaneous delivery of test aerosol to at least two of the test stations **20**. Alternatively, the test aerosol may not be delivered simultaneously.

10 Other variations in the methods and systems of the invention may include the delivery of different selected amounts of the test aerosol to different test stations **20** or the delivery of the same selected amount of test aerosol to different test stations **20** at different time intervals. These variations in the basic method may be used to accommodate simultaneous fit testing of test subjects at different 15 test stations **20** that exhibit different levels of aerosol sensitivity. Those different sensitivity levels may require exposure of the different test subjects to different concentrations of the test aerosol during the fit testing process. Changing the amount of test aerosol delivered by the automated aerosol generator system **30** and/or the time intervals at which those amounts are delivered may accommodate 20 those differences.

The fit testing methods may also optionally involve prompting the test subjects at the test stations **20** to perform specified activities during exposure to the test aerosol. Those activities may include, for example, normal breathing, deep breathing, side-to-side head movement, up-and-down head movement, 25 talking, bending at the torso, jogging in place, etc. The prompting may be provided by a test administrator **50** (if present) or by the system **10** itself (e.g., from controller **40**). Prompting may be simultaneously provided to at least two or more of the test subjects at the test stations **20**. Alternatively, the prompting may not be provided simultaneously.

30 The fit testing methods of the present invention may also optionally include receiving activity feedback from each of the test subjects. The activity

feedback may, for example, be indicative of the completion of one or more of the specified activities. This activity feedback may be helpful for those fit testing systems **10** in which the different test subjects at the different test stations can proceed through the fit testing process at different rates. For example, the
5 controller **40** and/or test administrator **50** may wait to receive an indication from the test subject that a prompted specified activity is complete before prompting that test subject to perform a different specified activity. The activity feedback may also be stored in the database where it is preferably correlated with the personal identification information of the test subject providing the activity
10 feedback.

In many qualitative fit testing processes, it may be necessary to establish the taste and/or smell response sensitivity of each test subject to aerosols. Different sensitivity levels may require exposure of that individual to different concentration levels of the test aerosol or aerosols. In connection with the present
15 invention, the sensitivity of each test subject may be established using systems and/or methods that do not fall within the scope of the present invention. For example, the test subjects may be pre-tested to determine their sensitivity levels, with that data being used in connection with the present invention. Alternatively, the systems and methods of the present invention may also advantageously
20 include determination of the test subjects' sensitivity levels by exposing the individuals to a sensitivity aerosol when they are not wearing a respirator.

If included in the present invention, it may be desirable, as a part of the fit test, that an automated aerosol generator system also be used to deliver a sensitivity aerosol to each of the test stations **20** occupied by a test subject,
25 thereby exposing each of the test subjects to the sensitivity aerosol. Sensitivity testing is typically performed when the test subject is not wearing a respirator. The automated aerosol generator system used to deliver the sensitivity aerosol may be the same as that used to deliver the test aerosol, or a different aerosol generator system may be used. Also, the sensitivity aerosol and the test aerosol
30 may be the same or different materials and/or concentrations.

It may be desirable to simultaneously deliver an initial selected amount of the sensitivity aerosol to each of the occupied test stations **20**. Alternatively, the delivery of sensitivity aerosol to the different test stations need not be simultaneous.

- 5 The method may also include receiving sensitivity feedback from the test subjects after exposure to the sensitivity aerosol. Sensitivity is often determined by exposing the test subjects at the occupied test stations **20** to increasing concentrations of the sensitivity aerosol. As a result, it may be desirable to prevent delivery of the sensitivity aerosol to a test station **20** occupied by a test
10 subject after that test subject has indicated that he or she has detected the sensitivity aerosol. Preventing further delivery of the sensitivity aerosol may increase the comfort of the test subjects.

- The sensitivity feedback may be used, in combination with the sensitivity aerosol delivery information, to set the concentration level of the test aerosol to
15 which the test subject should be exposed during the later portion of the fit test. It may be desirable to store the sensitivity feedback received and the sensitivity aerosol delivery information in the database and correlate that information with the personal identification information of the test subject to assist in setting the test aerosol concentration levels.

- 20 One illustrative embodiment of an alternative qualitative fit testing system **110** is depicted in more detail in FIG. 2. The system **110** includes multiple test stations **120** at which test subjects can be located during the fit testing process. The automated aerosol generator system **130** includes a set of independent test aerosol generators **134** used to generate test aerosol during fit testing. Each of the
25 test aerosol generators **134** is in fluid communication with one of the test stations **120**. In this configuration, the aerosol generator system **130** may be in “fluid communication” by providing a test aerosol generator **134** at each of the test stations **120**. For example, each test aerosol generator **134** may feed its aerosol directly into the enclosed volume defined by the test station **120**, without
30 requiring any fluid conduits or other fluid delivery apparatus.

As used herein, the term "set of independent aerosol generators" (and variations thereof) means a set of aerosol generators that can deliver aerosol independent of each other. For example, one or more aerosol generators can be operated while others are not operating, each of the aerosol generators can deliver
5 different amounts of aerosol at the same time, the aerosol generators can deliver different types of aerosols to the test stations, etc.

An optional set of independent sensitivity aerosol generators **136** is also depicted in FIG. 2, with each of the sensitivity aerosol generators **136** in fluid communication with one of the test stations **120**. Either set of independent
10 aerosol generators **134** or **136** may be replaced a central aerosol generator as depicted in connection with FIG. 1.

FIG. 2 also illustrates a controller **140** operably connected to the automated aerosol generator system **130** for controlling the delivery of aerosol to the test stations **120**. The controller **140** may be provided in any suitable form,
15 e.g., a hardwired control device or a data processing system, e.g., a personal computer or workstation that includes a processor, one or more display devices, one or more input devices, one or more data storage devices, and one or more printers or other output devices. In some instances, the controller may include a combination of one or more hardwired control devices and one or more data
20 processing systems.

The automated aerosol generator system **130** and controller **140** can be located remote from each other and connected by any suitable technique, e.g., modem, hardwire connection, radio control, computer network connection, etc. Alternatively, the automated aerosol generator system **130** and controller **140** may
25 be integrated into a single unit.

The test aerosol generators **134** and sensitivity aerosol generators **136** are operably connected to a power source **132** that provides the power necessary to operate the aerosol generators **134** and sensitivity aerosol generators **136**. The power source **132** may, for example, be in the form of a pressurized gas source
30 (e.g., air) if the aerosol generators **134** and optional sensitivity aerosol generators **136** are provided in the form of pressurized gas-powered nebulizers.

Alternatively, the aerosol generators **134** and **136** may be, e.g., piezo-electric nebulizers, sonic nebulizers, etc. Regardless of their specific construction, the aerosol generators **134** and **136** may provide monodispersed aerosols or they may provide polydispersed aerosols as desired or required by the test protocol being conducted.

The power source **132** is depicted as being connected to each of the test aerosol generators **134** individually through lines **133**. Each line **133** may include a power channel (e.g., fluid conduit for pressurized gas, cables for electrical power, etc.) and/or one or more signal lines. The signal line or line may operate a nebulizer, valve, etc. In this configuration of individual connections between power source **132** and test aerosol generators **134**, it may be possible to operate each of the test aerosol generators **134** independently. As a result, two or more of the test aerosol generators **134** may be operated simultaneously to deliver the same or different selected amounts of test aerosol to their respective test stations **120**.

Alternatively, the test aerosol generators **134** may be actuated at different times and/or may deliver different selected amounts of the test aerosol to their respective test stations **120**.

The sensitivity aerosol generators **136** are also connected to the power source **132**, but through a common line **135** as opposed to individual lines **133**. This configuration may be particularly amenable to simultaneous actuation of each of the sensitivity aerosol generators **136** to deliver sensitivity aerosol to each test station **120**. It may, however, be possible to prevent actuation of one or more of the sensitivity aerosol generators **136** if, for example, a test subject at one of the test stations **120** has already indicated detection of the sensitivity aerosol at a lower concentration.

FIG. 3 is a schematic representation of a database **60** that may be used in connection with the present invention. The database **60** may be stored on any suitable device and/or in any suitable manner, e.g., on the hard drive of computer, a CD-ROM, tape, diskette, in volatile memory, etc. The database **60** may be stored locally at the site of the fit testing system and/or at a remote location. For

example, the database **60** may be stored on a data storage device associated with the controllers described in connection with the systems of the present invention.

The database **60** may include a variety of information including, e.g., personal identification information of a test subject **61**, sensitivity feedback **62**,
5 sensitivity delivery information **63**, test feedback **64**, test aerosol delivery information **65**, at least one captured image **66**, and activity feedback **67**. The database **60** may include other types of information as well. In another alternative, the database may store, e.g., only a single piece of information regarding sensitivity of the test subject (as opposed to both sensitivity feedback
10 **62** and sensitivity aerosol delivery information **63**). It is preferred, but not required, that the information related to a specific test subject be correlated with the personal identification information **61** of that test subject in the database **60**.

The database **60** may serve a variety of purposes. For example, it may be used to improve respirator design by allowing a manufacturer to identify
15 respirators that generate larger numbers of fit test failures, it may be used to monitor compliance with fit testing requirements, etc.

The systems and methods of the present invention provide opportunities in the administration of respirator fit testing programs not previously available. Fig. 4 is a schematic diagram depicting a centralized test administrator **250**
20 operating a centralized fit test controller **270** in communication with multiple automated respirator fit testing systems **210**.

The controller **270** may be provided in any suitable form, e.g., a hardwired control device or a data processing system, e.g., a personal computer or workstation that includes a processor, one or more display devices, one or more
25 input devices, one or more data storage devices, and one or more printers or other output devices. In some instances, the controller **270** may include a combination of one or more hardwired control devices and one or more data processing systems.

The centralized fit test administrator **250** and associated controller **270**
30 may operate the different automated respirator fit testing systems **210** simultaneously or at different times. The centralized fit test administrator **250**,

and central controller **270** may be located at sites remote from each other and the automated respirator fit testing systems **210**. As used herein, “operate” (and variations thereof), means that the administrator **250** controls the remote automated respirator fit testing systems **210** in a manner that allows the
5 administrator **250** to initiate, monitor, and/or terminate respirator fit tests being conducted by the systems **210** at the remote sites.

The test administrator **250** and controller **270** may be linked to the fit testing systems **210** by any suitable technique that offers the required level of data transmission, e.g., modem, hardwire connection, radio control, computer network
10 connection, etc. It may further be preferred that the test administrator **250** and controller **270** be capable of conducting respirator fit tests at two or more of the fit testing systems **210** at the same time.

The automated respirator fit testing systems **210** themselves may include two or more test stations and be capable of simultaneously fit testing multiple
15 individuals. Alternatively, one or more of the respirator fit testing systems **210** may be supplied with only one test station. Regardless of whether the fit testing systems **210** are capable of processing only one test subject at a time or more than one test subject simultaneously, the opportunity for remote administration of respirator fit tests may offer the advantages of increased access to test
20 administrators and potentially lower cost fit testing.

As part of the remote administration of respirator fit tests, operation of the automated respirator fit testing systems may include receiving test feedback at the site of the administrator **250** and/or central controller **270** from a test subject at one of the fit testing systems **210** after exposure to the test aerosol. Alternatively,
25 the test feedback may be received locally at the site of the automated respirator fit testing system **210** at which the test is being conducted.

Regardless of where received, the test feedback may be stored in a database as discussed above. The database may be located in a device that forms a part of the respirator fit testing system **210** at the testing site, in a device that
30 forms a part of the central controller **270**, in a device at the location of the administrator **250**, and/or in some other location. Remote administration may

also involve storing information regarding the test aerosol delivery during fit testing in the database.

Remote administration of a respirator test may also include monitoring the test stations at which respirator fit tests are being performed. In addition to 5 monitoring, remote administration may also include capturing at least one image during the monitoring. That captured image (or images) may also be stored in one or more databases as discussed above.

Prompting of test subjects at the different sites of the test systems may also be a part of remote respirator fit test administration. For example, a test 10 administrator **250** may prompt the subjects to perform specified activities as a part of the fit tests, the central controller **270** may generate prompts once the test has been initiated, or the local automated respirator fit testing system **210** may generate the prompts. In some instances, it may be desirable to allow the prompts to originate from more than one location. For example, it may be desirable to 15 deliver the prompts from the local test system **210**, but to allow the administrator **250** to deliver additional prompts as deemed necessary. Remote test administration may also include receiving activity feedback from the test subjects indicating completion of the specified activities and in a manner similar to receipt (and optional storage) of test feedback described above.

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The preceding specific embodiments are illustrative of the practice of the invention. This invention may be suitably practiced in the absence of any element or item not specifically described in this document. The complete disclosures of all patents, patent applications, and publications are incorporated into this 25 document by reference as if individually incorporated in total.

Various modifications and alterations of this invention will become apparent to those skilled in the art without departing from the scope of this invention, and it should be understood that this invention is not to be unduly limited to illustrative embodiments set forth herein, but is to be controlled by the 30 limitations set forth in the claims and any equivalents to those limitations.

What is claimed is:

1. A method of qualitative respirator fit testing, the method comprising:
 - providing an automated qualitative respirator fit testing system that comprises a plurality of test stations and an automated aerosol generator system
 - 5 in fluid communication with each of the test stations;
 - locating at least one test subject at one test station of the plurality of test stations; and
 - conducting a qualitative fit test on each test subject located at one of the test stations, wherein the qualitative fit test conducted at each of the test stations
- 10 comprises:
 - delivering a test aerosol to the test station using the automated aerosol generator system after locating a respirator on the test subject, wherein the test subject is exposed to the test aerosol; and
 - 15 receiving test feedback from the test subject at the test station after exposure to the test aerosol.
2. The method of claim 1, further comprising locating two or more test subjects at the plurality of test stations and conducting a qualitative fit test on each of the two or more test subjects simultaneously.
- 20
3. The method of claim 2, wherein delivering the test aerosol further comprises simultaneous delivery of the test aerosol to the two or more test subjects
- 25
4. The method of claim 1, wherein the automated aerosol generator system comprises a set of independent aerosol generators, with at least one of the independent aerosol generators in fluid communication with each of the test stations.

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5. The method of claim 1, wherein the aerosol generator system comprises at least one aerosol generator in fluid communication with at least two of the plurality of test stations.
 - 5 6. The method of claim 1, wherein providing the test aerosol further comprises delivering a selected amount of the test aerosol to each of the test subjects at predetermined intervals using the aerosol generator system.
 - 10 7. The method of claim 6, further comprising delivering the selected amount of the test aerosol to each of the test subjects simultaneously.
 8. The method of claim 6, further comprising delivering different selected amounts of the test aerosol to at least two of the test stations.
 - 15 9. The method of claim 1, further comprising storing the test feedback in a database.
 10. The method of claim 1, further comprising storing information regarding the test aerosol delivery to each of the test subjects in a database.
 - 20 11. The method of claim 1, further comprising monitoring each of the test stations during exposure of the test subjects to the test aerosol.
 12. The method of claim 1, further comprising:
25 monitoring each of the test stations during exposure of the test subject to the test aerosol to each of the test stations;
capturing at least one image during the monitoring;
storing the at least one image in a database.

13. The method of claim 1, further comprising prompting the test subjects at each of the test stations to perform specified activities during exposure of the test subject to the test aerosol.
- 5 14. The method of claim 13, further comprising simultaneous prompting of at least two test subjects to perform the specified activities.
- 10 15. The method of claim 13, further comprising receiving activity feedback from each of the test subjects indicating completion of the specified activities.
16. The method of claim 1, wherein the qualitative fit test performed at each of the test stations further comprises:
- 15 delivering sensitivity aerosol to the test station using the automated aerosol generator system, wherein the test subject is exposed to the sensitivity aerosol; and
- receiving sensitivity feedback from the test subject at the test station after exposure to the sensitivity aerosol.
- 20 17. The method of claim 16, further comprising simultaneous delivery of an initial selected amount of the sensitivity aerosol to each of at least two test subjects.
- 25 18. The method of claim 16, further comprising preventing delivery of the sensitivity aerosol to at least one test subject after receiving sensitivity feedback from the test subject indicating detection of the sensitivity aerosol by the test subject after delivering the initial selected amount of the sensitivity aerosol.
- 30 19. The method of claim 16, further comprising storing the sensitivity feedback in a database.

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20. The method of claim 16, further comprising storing information regarding
the sensitivity aerosol delivery to each of the test subjects in the database.
21. A qualitative respirator fit testing system comprising:
5 a plurality of test stations; and
an automated aerosol generator system in fluid communication with each
of the test stations.
22. The system of claim 21, wherein the automated aerosol generator system
10 comprises a set of independent aerosol generators, wherein at least one of the
independent aerosol generators is in fluid communication with each of the test
stations.
23. The system of claim 22, wherein each of the aerosol generators comprises
15 a nebulizer.
24. The system of claim 21, wherein the automated aerosol generator system
comprises at least one aerosol generator in fluid communication with at least two
of the plurality of test stations.
20
25. The system of claim 21, wherein each of the test stations comprises a
respirator fit testing hood.
26. A method of remote automated respirator fit testing comprising:
25 providing an automated respirator fit testing system at a first location,
wherein the automated respirator fit testing system comprises at least one test
station and an automated aerosol generator system in fluid communication with
each of the at least one test stations;
locating at least one test subject wearing a respirator at the test station of
30 the respirator fit testing system at the first location; and

- operating the automated respirator fit testing system from a remote location to perform a respirator fit test on the at least one test subject by delivering a test aerosol to the at least one test station using the automated aerosol generator system, wherein the at least one test subject is exposed to the test aerosol.
- 5
27. The method of claim 26, wherein operating the respirator fit testing system comprises receiving test feedback at the remote location from the test subject at the first location after exposure to the test aerosol.
- 10
28. The method of claim 27, further comprising storing the test feedback in a database.
- 15
29. The method of claim 26, further comprising storing information regarding the test aerosol delivery in a database.
30. The method of claim 26, further comprising monitoring the at least one test station while performing the respirator fit test.
- 20
31. The method of claim 26, further comprising:
monitoring the at least one test station while performing the respirator fit test;
capturing at least one image during the monitoring;
storing the at least one image in a database.
- 25
32. The method of claim 26, further comprising prompting the at least one test subject to perform specified activities while performing the respirator fit test.
- 30
33. The method of claim 26, further comprising receiving activity feedback from the at least one test subject indicating completion of the specified activities while performing the respirator fit test.

34. The method of claim 26, further comprising simultaneous prompting of at least two test subjects to perform the specified activities.

- 5 35. The method of claim 26, further comprising:
providing a second automated respirator fit testing system at a second location remote from the first location, wherein the second automated respirator fit testing system comprises at least one test station and an automated aerosol generator system in fluid communication with each of the at least one test
10 stations;
locating at least one test subject wearing a respirator at the test station of the second automated respirator fit testing system at the second location; and
operating the first and second automated respirator fit testing systems from the remote location to perform a respirator fit test on the at least one test
15 subject located at each of the first and second automated respirator fit testing systems, wherein each respirator fit test comprises delivering a test aerosol to the at least one test station using the automated aerosol generator system, wherein the at least one test subject is exposed to the test aerosol.
- 20 36. The method of claim 35, further comprising conducting respirator fit tests using the first and second automated respirator fit testing systems at the same time.

RESPIRATOR FIT TESTING METHODS AND SYSTEMS

5

Abstract of the Disclosure

A system and method for the remote administration of respirator fit tests are disclosed, along with a system and method for administering qualitative respirator fit tests to two or more test subjects simultaneously. Remote administration of respirator fit tests involves the testing of test subjects located at 10 one facility by a test administrator located at a different facility. The two facilities may be located, for example, in the same city, in different countries, etc. As a result, a single test administrator may, for example, be able to administrate fit tests with test subjects located in a variety of facilities in one day without traveling. Qualitative respirator fit testing systems and methods of the invention 15 include multiple test stations and an aerosol generator system in fluid communication with each of the test stations. The aerosol generator system may be capable of delivering aerosol to the test stations in repeatable, selected amounts and may also be capable of delivering the aerosols to some or all of the stations simultaneously.

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PRINTED NAME Rachel Gagliardi-Graham

SIGNATURE Rachel Gagliardi-Graham

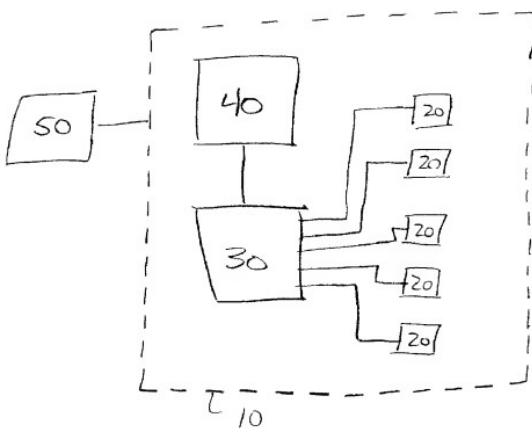


FIG. 1

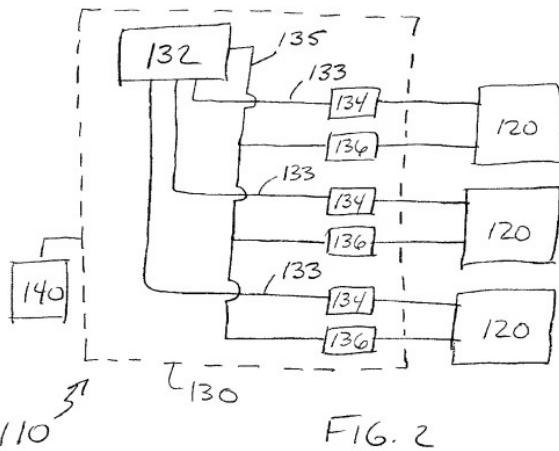
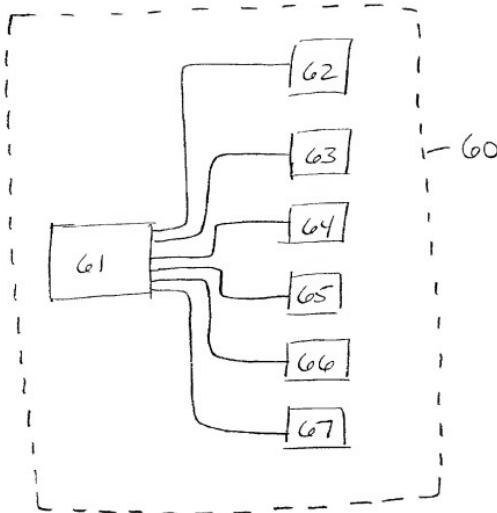
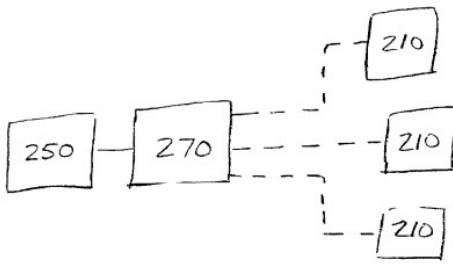


FIG. 2

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F16.3



F16.4

DECLARATION, POWER OF ATTORNEY, AND PETITION

I, a below named inventor, depose and say that: (1) my residence, citizenship, and mailing address are indicated below; (2) I have reviewed and understand the contents of attached specification, including the claims, as amended by any amendment specifically referred to herein, (3) I believe that I am the original, first, and sole inventor or discoverer of the invention or discovery in

AUTOMATED RESPIRATOR FIT TESTING METHOD AND SYSTEM

described and claimed therein and for which a patent is sought; and (4) I hereby acknowledge my duty to disclose to the Patent and Trademark Office all information known to me to be material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56.*

I hereby appoint Gregory D. Allen (Reg. No. 35,048), Alan Ball (Reg. No. 42,286), Scott A. Bardell (Reg. No. 39,594), Carolyn A. Bates (Reg. No. 27,853), Stephen W. Bauer (Reg. No. 32,192), Dale A. Bjorkman (Reg. No. 33,084), Colene E. H. Blank (Reg. No. 41,056), Jennie G. Boeder (Reg. No. 28,952), William J. Bond (Reg. No. 32,400), Stephen W. Buckingham (Reg. No. 30,035), John A. Burts (Reg. No. 39,924), Paul W. Busse (Reg. No. 32,403), Gerald F. Chernivec (Reg. No. 26,537), James D. Christoff (Reg. No. 31,492), Philip Y. Dahl (Reg. No. 36,115), Janice L. Dowdall (Reg. No. 31,201), Lisa M. Fagan (Reg. No. 40,601), Carolyn A. Fischer (Reg. No. 39,091), Yen T. Florcak (Reg. No. 45,163), Darla P. Fonseca (Reg. No. 31,783), John A. Fortkort (Reg. No. 38,454), Melanie G. Gover (Reg. No. 41,793), Christopher D. Gram (Reg. No. 43,643), Gary L. Griswold (Reg. No. 25,396), Doreen S. L. Gwin (Reg. No. 35,580), Michaela A. Hakamaki (Reg. No. 40,011), Karl G. Hanson (Reg. No. 32,900), Néstor F. Ho (Reg. No. 39,460), Rudolph P. Hofmann, Jr. (Reg. No. 38,187), Jeffrey J. Hohenshell (Reg. No. 34,109), Robert W. Hoke (Reg. No. 29,226), MarySusan Howard (Reg. No. 38,729), Stephen C. Jensen (Reg. No. 35,207), Robert H. Jordan (Reg. No. 31,973), Harold C. Knecht III (Reg. No. 35,576), Kent S. Kokko (Reg. No. 33,931), Charles D. Levine (Reg. No. 32,477), Douglas B. Little (Reg. No. 28,439), Eloise J. Maki (Reg. No. 33,418), Lisa M. McGehee (Reg. No. 41,185), Matthew B. McNutt (Reg. No. 39,766), Michelle M. Michel (Reg. No. 33,968), William D. Miller (Reg. No. 37,988), Peter L. Olson (Reg. No. 35,308), Daniel R. Pastirik (Reg. No. 33,025), David B. Patchett (Reg. No. 39,326), Robert J. Pechman (Reg. No. 45,002), Carolyn V. Peters (Reg. No. 33,271), Scott R. Pribnow (Reg. No. 43,869), Ted K. Ringsred (Reg. No. 35,658), James A. Rogers (Reg. No. 37,228), Steven E. Skolnick (Reg. No. 33,789), Robert W. Sprague (Reg. No. 30,497), Brian E. Szymanski (Reg. No. 39,523), James J. Trussell (Reg. No. 37,251), Lucy C. Weiss (Reg. No. 32,834), and Kimberly S. Zillig (Reg. No. 46,346) Kevin W. Raasch, (Reg. No. 35,651), my attorneys and/or agents with full powers (including the powers of appointment, substitution, and revocation) to prosecute this application and any division, continuation, continuation-in-part, reexamination, or reissue thereof, and to transact all business in the Patent and Trademark Office connected therewith; the mailing address and the telephone number of the above-mentioned attorneys and/or agents are

Attention: Karl G. Hanson
Office of Intellectual Property Counsel
3M Innovative Properties Company
P.O. Box 33427
St. Paul, Minnesota 55133-3427
Telephone No. 651-736-7776

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Wherefore, I pray for grant of Letters Patent for the invention or discovery described and claimed in the attached specification and I hereby subscribe my name to the foregoing specification and claims, declaration, power of attorney, and this petition, on the day set forth below.

Haskell E. Mullins 10/26/00
Haskell E. Mullins
Residence: Cottage Grove, Minnesota, U.S.A.
Citizenship: U.S.A.
Post Office: P.O. Box 33427
Address: St. Paul, Minnesota 55133-3427

*Title 37, Code of Federal Regulations, §1.56 is attached.

This form may be executed only when attached to the specification (including claims) as the last page thereof.

Paul A. Martin 10/26/00

Date

Paul A. Martinson

Residence: Maplewood, Minnesota, U.S.A.

Citizenship: U.S.A.

Post Office P.O. Box 33427

Address: St. Paul, Minnesota 55133-3427

MRJ

10/26/00

Date

Alan R. Johnston

Residence: West St. Paul, Minnesota, U.S.A.

Citizenship: U.S.A.

Post Office P.O. Box 33427

Address: St. Paul, Minnesota 55133-3427

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§1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.